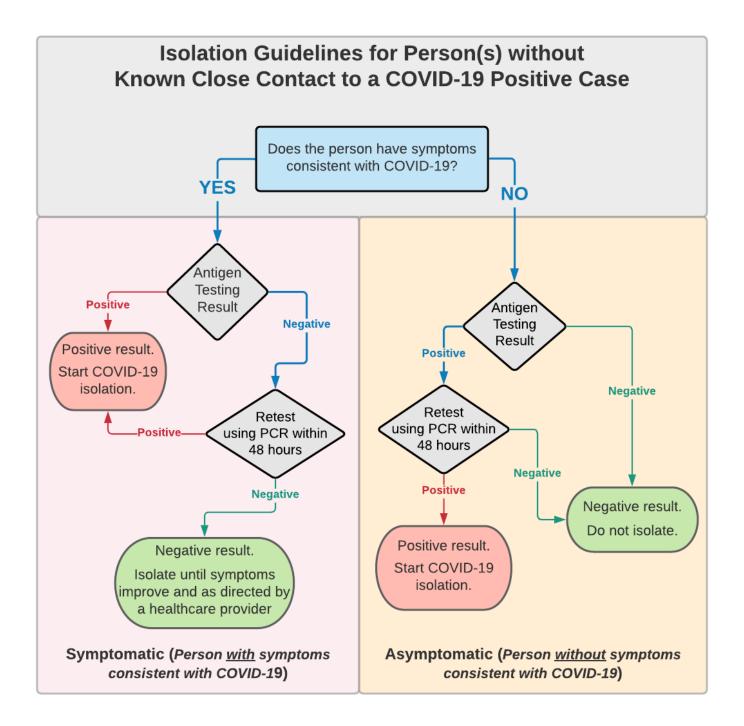


Protecting and Improving the Health of Iowans

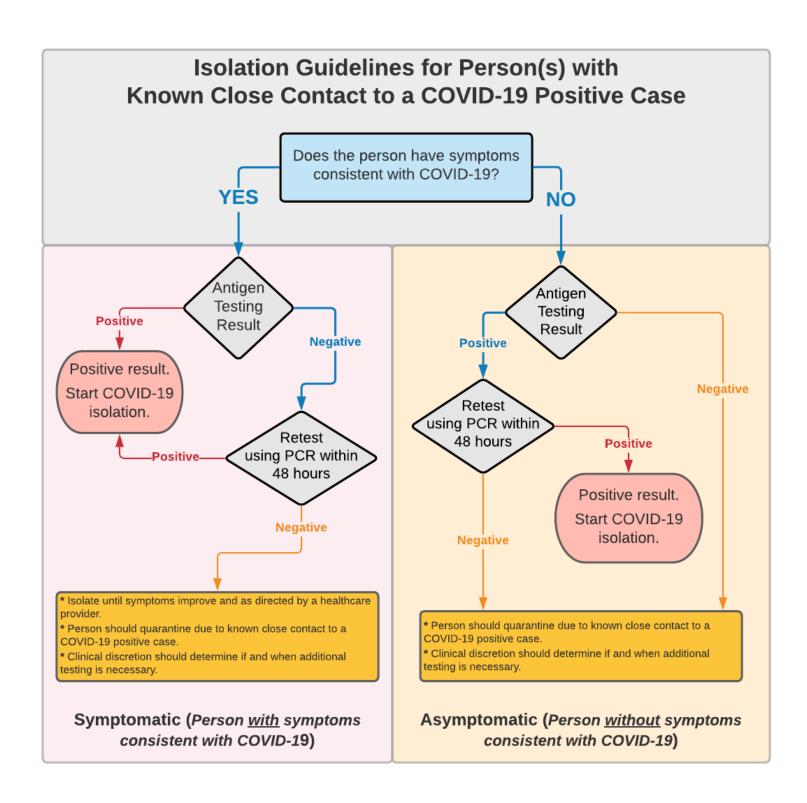
Kim Reynolds, Governor

Adam Gregg, Lt. Governor

Kelly Garcia, Interim Director



This guidance is subject to change as federal guidance is released and clarified, and as additional lowa-specific data is collected. Page ${\bf 1}$ of ${\bf 3}$



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Antigen Testing Technical Pointers:

- Thoroughly read the package insert before performing the test and follow all instructions.
- Store reagents at the recommended temperatures and bring refrigerated reagents to room temperature before use
- Change gloves between each patient specimen to avoid cross contamination
- **DO NOT** use viral transport media.
- Test samples within the specified time after collection. For example, BinaxNOW cards must be tested within 1 hour of collection.
- **DO NOT** use expired reagents or damaged test cassettes/devices.
- Document proper timing for reading the results when testing multiple specimens at the same time.
- Use the test cassette/device within specified time after opening.
- ALWAYS keep the test device in a horizontal position when in use.
- Results must be interpreted within specified times frames. For example, BinaxNOW cards must be read promptly at 15 minutes after the swab is inserted. Do not read results before 15 minutes or after 30 minutes and record the time the results were read.
- Read results exactly as described in the package insert.
- When complete and between samples, disinfect work surfaces and equipment with an <u>EPA-approved</u> disinfectant for SARS-CoV-2.
- To document competency have staff view the relevant video:
 - BinaxNOW: https://www.youtube.com/watch?v=nYTePdZBbLU
 - o BD Veritor: https://www.youtube.com/watch?v=wJJRPS7pu44
 - Quidel Sofia: https://www.youtube.com/watch?v=D7xJ2LQ4IV4

Missing Swabs from Antigen Kits:

For all emergency use authorization (EUA) cleared test systems the laboratory must follow the instructions for use (IFU). Laboratories must follow collection procedures as written. For example:

- If the IFU states a nasopharyngeal (NP) swab must be used to perform the test, the lab cannot collect a nasal swab to perform the test if NP swabs are not available.
- If the IFU states to use NP swab, but does not list a specific brand, then the laboratory is free to use any NP swab available.

A more specific example is the Abbott ID Now, the IFU states, "For optimal test performance, use the swabs provided in the test kit. Alternatively, foam, polyester, HydraFlock® and nylon flocked throat swabs can be used to collect throat swab samples. Rayon swabs are not suitable for use in this assay." In this case, the laboratory could not use Rayon swabs, but any of the others listed would be acceptable. The IFUs are different for each test system, so be sure to review the entire IFU. — submitted by Kristi Rotzoll, CLIA Compliance Specialist

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